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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a process to allow the holders of abbreviated new drug applications to make labeling changes to include new or updated safety-related information, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MCEACHIN introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a process to allow the holders of abbreviated new drug applications to make labeling changes to include new or updated safety-related information, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Updated Drug Label-
3 ing for Patient Safety Act”.

4 **SEC. 2. SAFETY LABELING CHANGES INITIATED BY ANDA**
5 **HOLDERS.**

6 (a) IN GENERAL.—Section 505(j) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is
8 amended by adding at the end the following:

9 “(14) Notwithstanding paragraphs (2)(A)(v), the
10 Secretary shall establish a process to allow the holder of
11 an abbreviated new drug application to change the labeling
12 of the drug that is the subject of the application to include
13 new or updated safety-related information, including a
14 process to make such changes prior to being approved by
15 the Secretary.”.

16 (b) REGULATIONS.—

17 (1) IN GENERAL.—Not later than 18 months
18 after the date of enactment of this Act, the Sec-
19 retary of Health and Human Services shall issue a
20 final rule to implement paragraph (14) of section
21 505(j) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 355(j)), as added by subsection (a).

23 (2) CONTENTS.—The final rule issued under
24 paragraph (1) shall include a process for conforming
25 the labeling of a drug that is labeled pursuant to
26 such paragraph (14), the listed drug (as such term

1 is used in such section 505(j)), and other drugs ap-
2 proved under such section 505(j) that reference such
3 listed drug.

4 (3) EFFECTIVE DATE.—The final rule issued
5 under paragraph (1) shall become effective not later
6 than 180 days after the date on which such final
7 rule is issued.